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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,986	10/14/2003	Howard I. Katz	17610 (BOT)	7095

7590 05/10/2007
Andrew M. Blumfield, M.D.
The Headache Center of Southern California
Encinitas, CA 92024

EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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05/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/685,986

Applicant(s)

KATZ ET AL.

Examiner

Donna Jagoe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in this application.

Applicants' arguments filed October 31, 2006 have been fully considered and they are deemed to be persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application. The amendment filed October 31, 2006 has been received and entered. Claims 1, 10, 15, 17 and 19 have been amended.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Perel (U) Nissani U.S. Patent No. 6,164,278 A and Borodic U.S. Patent No. 5,298,019 and in further view of Odergren et al. (V).

Perel teaches that parafunctional habits, such as clenching and bruxism are potentially destructive to implant prosthodontic components, causing destruction of bone around implants (page 261). These parafunctional occlusal forces are usually imparted to prostheses nocturnally and can lead to tooth loss. Perel does not teach administration of botulinum toxin.

Nissani teaches that sleep bruxism exerts powerful forces on teeth, gums and joints and causes adverse effects to dental implants and aesthetic restorations (column 1, lines 40-67). Nissani further teaches that some approaches to treat bruxism and clenching involve muscle relaxers, such as magnesium administration (column 4, lines 49-56). Although Nissani teach that muscle relaxers are contemplated, it does not teach administration of botulinum toxin.

Borodic provides motivation to employ a chemodenervating agent such as to botulinum toxin derived preparations (column 2, lines 36-40), injected into the muscles

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activating the jaw (muscles of mastication) to retard tooth wear caused by involuntary or unconscious clenching of teeth (column 4, lines 18-21). Any type of botulinum toxin may be employed (A through G) (column 3, lines 58-63).

Borodic differs in that it does not teach specifically facilitating an adherence of a dental item to a substrate in the mouth of a patient, however Perel teaches that bruxism and clenching can cause destruction of implants and prosthetic components and Nissani teach that bruxism exerts powerful forces on teeth and gums and is harmful for implants and aesthetic restorations. It would have been made obvious to one of ordinary skill in art at the time it was made to administer botulinum toxin to weaken a muscle of mastication to facilitate the adherence of a dental item, facilitate adherence of a tooth substrate, accelerate adherence of transplanted gum tissue to a substrate in the mouth of a patient and obtain an optimal oral neuromuscular position motivated by the teachings of Borodic that inhibition of jaw clenching protects the teeth when botulinum toxin is administered to the masseter, temporalis and pterygoid muscles (muscles of mastication) of a patient (column 9, lines 30-46). And Perel and Nissani who teach that clenching and bruxism is harmful to prosthetics, gums and aesthetic restorations. In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, Perel disclose that bruxism and clenching

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can cause destruction of implants and prosthetic components. Nissani teach the destructive effect to prosthetics, gums and aesthetic restorations. Borodic discloses inhibition of tooth wear by administration of a chemodenervating agent such as to botulinum toxin derived preparations (column 2, lines 36-40), injected into the muscles activating the jaw (muscles of mastication), such as the masseter, temporalis and pterygoid muscles, to retard tooth wear caused by involuntary or unconscious clenching of teeth (column 4, lines 18-21). In addition, by the time of the claimed invention, botulinum toxin was a well-known and successful chemodenervating agent used in attenuating spasmodic activity of muscle (see Borodic, column 1, line 10 to column 2, line 2). Accordingly, there was clear motivation to employ a botulinum toxin to weaken the muscles of mastication to reduce the bite force that could damage a dental restoration, gum transplant or obtain an optimal oral neuromuscular position when the patients bite position was suboptimal and resulted in damage to the teeth by clenching/grinding. Regarding the dosage of about 1 unit and about 10,000 units, Borodic teaches administration of between a few units to about 1000 units, which is encompassed by the claims dosage amount. Further, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity. For these and other self-evident reasons, it would have been obvious to use between about 1 unit and about 10,000 units of botulinum toxin.

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Regarding the period of time of claims 6 and 14, Odergren et al. teach that the pharmacodynamic properties of botulinum toxin are such that the onset of action is usually evident within two weeks of treatment and the peak effect occurs at four to eight weeks when injected into muscles for cervical dystonia (see page 11, column 2 2nd full paragraph). This time period overlaps and partially encompasses the claimed time period of between one hour and thirty days.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

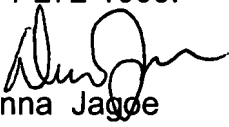
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Donna Jagoe
Patent Examiner
Art Unit 1614

May 4, 2007

 5/6/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER